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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,468	07/24/2000	Lee Arnold	BBI-6049	4509

959 7590 11/15/2001

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EXAMINER
KIFLE, BRUCK

ART UNIT	PAPER NUMBER
1624	13

DATE MAILED: 11/15/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/621,468	Arnold et al.
Examiner	**Art Unit**
Bruck Kifle	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 17, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above, claim(s) *1-17 and 22* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-21 and 23-45* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4 and 5*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Election/Restriction

Applicant's election with traverse of group VII (claims 18-21 and 23-45, drawn to the compound of claim 18, pharmaceutical composition and method of use, classified in various classes and subclasses depending on the nature of R and R^1) and the compound 3-cyclopropyl-4-[(4,5-dimethylpyrolo-2-yl)-methylene]-2-pyrazolin-5-one in Paper No. 8 is acknowledged. The traversal is on the grounds that the species are different embodiments of a single inventive concept and that the search of the entire application can be done without serious burden. This is not found persuasive because, in fact, even the compounds of claim 18 are structurally so dissimilar compounds, which are made and used independently, and are patentably distinct. If, say a compound wherein R is phenyl (classified in class 548, subclass 364.1), were anticipated, applicants would not acquiesce in the rejection of a compound wherein R is pyrimidinyl (classified in class 544, subclass 333) thereover or vice-versa. The search required to search the entire claim 18 would be unduly burdensome. The basis of this restriction requirement is the same as given in the previous office action and is incorporated herein fully by reference. Compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept and will be rejoined and examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17 and 22 are withdrawn from consideration as being drawn to a non-elected group.

Improper Markush Rejection

Claims 18-21 and 23-45 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variables R and R^1 are defined in such a way that they keep changing the core of the compound that determines the classification. By changing these values, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula of claim 18 does not have a significant structural feature that is shared by all of its alternatives which is inventive. The structure has only a pyrazolinone as common. Compounds embraced by claim 18 are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions. See, for example, Blum et al. (US 6,107,487) which teaches R as thiazolyl (RN 250343-32-9P); Brick et al. (US 5,709,983) which teaches R as pyrazol (RN 188864-62-2); Hiremath et al. (Indian J. Chem., Sect. B (1988), 27B(8), 758-62) which teaches R as indole and Mitra et al. (Acta Cienc. Indica, Chem. (1985), 11(4), 267-72) which teaches a benzene ring at R (see CAS abstract and structures). All of these reference anticipate non-elected subject matter of claim 18.

Limiting the claims to the elected group (where R is pyrrolyl) would overcome this rejection.

The search was limited to embrace compounds wherein R is pyrrolyl.

Claim Rejections - 35 USC § 112

Claim 18-21 and 23-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) In claim 18, the phrase "and physiologically acceptable salts" should be written in the alternative as "or physiologically acceptable salts" to be of propre Markush form.

ii) The groups at R as written as molecules. This is incorrect. These groups should be written as radicals, such as, phenyl not benzene and pyrrolyl not pyrrole. Appropriate correction is required. (See also groups at Z). Also, the groups benzoindole and azaindole need clarification as these are not normal nomenclature. Similarly in Z, it is unclear which triazine is intended.

iii) The term "substituted" without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not.

iv) In claims 28-36 it is unclear what is intended. Which protein kinase activity is inhibited and which one is not? Why would one want to do that and when would this be done. It is unclear whether in vivo or in vitro is intended.

v) In claim 29 the recipient is not known.

vi) In claim 37 it is unclear how hyperproliferative disorders are affected or which hyperproliferative disorders are intended.

vii) Similarly, in claim 38 it is unclear which angiogenesis is being affected.

Regarding claim 22, Applicants are advised to see MPEP rule 1.141(a) reproduced below.

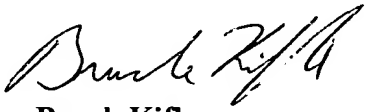
§ 1.141 Different inventions in one national application.
(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (1.75) or otherwise include all the limitations of the generic claim.

Claim 22 has 67 pages of compounds (approximately 2000 species). This number of compounds cannot be considered "a reasonable number" according to rule 1.140(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

November 8, 2001



Bruck Kifle
Primary Examiner
Art Unit 1624